REMARKS / ARGUMENTS

The pending claims are 1, 2, 4, 5, 15 and 17. Claim 22 is amended. Claims 3, 6-14, 16 and 18-19 are cancelled without prejudice or disclaimer, and Applicants reserve the right to pursue this subject matter in subsequent applications. Claims 20-24 are withdrawn, but awaiting rejoinder, assuming that some subject matter in the pending claims is found allowable. The specification has been amended on pages 7 and 12. No new subject matter has been added.

The specification was subject to an objection for failing to list sequence identity numbers for the ten nucleic acid sequences recited in Table 1 on page 12 of the present application. Applicants have hereby amended Table 1 to include sequence identity numbers. Thus, it is respectfully submitted that this objection is now moot.

Claims 1, 4 and 5 stand rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement. The Examiner specifically alleged that the present invention requires the depositing of a sample of the claimed bacterial artificial chromosome vector, and the inclusion of the information concerning the deposit as required by 37 CFR § 1.809 (d).

Applicants have hereby amended page 7 of the present specification to include the date of deposit, the name and address of the depositor, a statement that the deposit is capable of reproduction and the date of the viability test. Applicants have also attached a copy of the certificate of deposit, which specifically indicates that the deposit occurred on March 27, 2001 and was in accord with the Budapest Treaty of 1977, and a statement by the depositor that an artificial chromosome vector RacH-BAC was deposited and will be available to the public in accordance with the Budapest Treat of 1977. Based upon this evidence, the Applicants' attorney hereby states that to the best of her knowledge, after reasonable inquiry, the artificial chromosome vector RacH-BAC has been deposited in accordance with the Budapest Treaty of 1977, and will be available to the public upon

issuance of a patent based on the present application. Therefore, it is respectfully suggested that this rejection is moot and should be withdrawn.

Claims 1, 2, 4, 5, 15 and 17 stand rejected under 35 U.S.C. § 103(a) for allegedly being *prima facia* obvious in view of McGregor et al. (Molecular Genetics and Metabolism, Vol. 72(1), 2001, pp. 8-14) and Neubauer et al. (Virology, Vol. 239(1), 1997, pp. 36-45), respectively "McGregor" and "Neubauer" hereinafter.

The Examiner states that McGregor discloses BAC as a tool to express the gnome of numerous herpes viruses, such as HSV-1, which is an alphaherpesvirus, and the therapeutic properties that the mutated virus may possess. However, this reference does not teach the BAC of the claimed invention, which expresses EHV-1 RacH or expresses a gM deficient EHV-1 RacH virus.

Neubauer, as indicated by the Examiner, teaches vaccination protection from EHV-1 challenge, and discusses the potential of EHV-1 RacL11 and RacH mutants that do not express gM or gB in providing protective immunity.

Based upon this, the Examiner has concluded that it would have been obvious for a skilled artisan to modify the composition disclosed in McGregor to express related alphaherpesviruses in a BAC, thereby obtaining a BAC that expresses a specific gM deficient strain of EHV-1, such as RacH.

A *prima facia* case of obviousness requires that there be a motivation or suggestion to combine the references, a reasonable expectation of success and teach all of the limitation of claims being rejected. However, there cannot be a reasonable expectation of success if the proposed modification renders the prior art unsuitable for its intended purpose. See MPEP 2143.01. In the present case, if a skilled artisan had attempted to combine the teachings of McGregor with Neubauer they would <u>not</u> have arrived at the present invention, because McGregor does not disclose or suggest using cycloheximide when preparing and extracting circular DNA to block early viral transcription. The present specification points out that this problem was a major difficulty that had to be overcome:

> The generation of said BAC was not trivial and was posed many difficulties, including the preparation and extraction of sufficient amounts of circular DNA. The circularized form of recombinant viral DNA was needed to transform DH10B cells with the recombinant DNA in order to prepare the mini F plasmid-cloned EHV DNA. To obtain sufficient amounts of circular viral DNA, early viral transcription was blocked by the addition of 100 μg per ml of cycloheximide after infection of cells. Viral DNA was then prepared and used for transformation of DH10B cells. Only from cells treated with cycloheximide was it possible to extract sufficient amounts of circular DNA and to obtain DH10B clones containing the enitre RacH genome.

See present specification at page 5, lines 9-17, emphasis added. Therefore, because of this technical difficulty, the overcoming of which is not taught or suggested in the prior art, it can not be said that present invention as claimed is obvious, since one skilled in the art combining the cited references would fail to achieve the claimed invention. Additionally, the results of the combination would be a product not suitable for the intended purpose of the present invention, and therefore, there cannot be a reasonable expectation of success pursuant to MPEP 2143.01. Thus, the combination of McGregor and Neubauer does not form a *prima facia* case of obvious against the present invention as claimed. Accordingly, Applicants respectfully request that the Examiner withdraw this rejection.

Claim 22 has been amended to correct a typographical error. The dependency of claim 22 has been amended; it now depends from claim 1. Support for this amendment can be found generally throughout the specification.

Applicants believe the claims now form for allowance. Accordingly, Applicants respectfully request reconsideration and a judicious issuance of the present application. If there are any issues that can be better resolved by a telephonic or in-person interview, please contact Applicants' undersigned attorney at the below recited telephone number.

Respectfully submitted,

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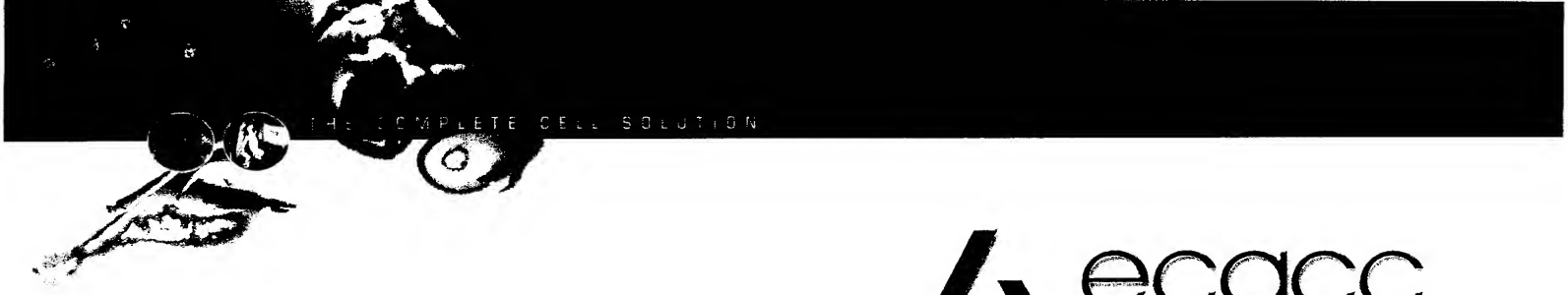
/Mary-Ellen M. Devlin/
Mary-Ellen M. Devlin, Reg. No. 27,928
Attorney for Applicant(s)



ecacc
European Collection
of Cell Cultures

Centre for Applied Microbiology and Research
&
European Collection of Cell Cultures

This document certifies that DNA
(Deposit Ref. 01032704) has been accepted as a patent deposit,
in accordance with
The Budapest Treaty of 1977,
with the European Collection of Cell Cultures on 27TH March 2001

. . . . . .

Dr D H Lewis
General Business Manager, ECACC

CAMR
Today's Research
Tomorrow's Health

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BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

TO
Dr N Osterrieder
Federal Research Centre
for Virus Diseases of Animals
Institue of Molecular Biology
Bodden Blick 5A
Insel Riens
D-17498
Germany

NAME AND ADDRESS
OF DEPOSITOR

I. IDENTIFICATION OF THE MICROORGANISM

Identification reference given by the DEPOSITOR:
RACH-BAC

Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:
01032704

II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION

The microorganism identified under I above was accompanied by:

[x] A scientific description

[ ] A proposed taxonomic designation

(Mark with a cross where applicable)

III. RECEIPT AND ACCEPTANCE

This International Depository Authority accepts the microorganism identified under I above, which was received by it on 27 March 2001 (date of the original deposit)[1]

IV. RECEIPT OF REQUEST FOR CONVERSION

The microorganism identified under I above was received by this International Depository Authority on (date of the original deposit) and
A request to convert the original deposit to a deposit under the Budapest Treaty was received by it on (date of receipt of request for conversion)

IV. INTERNATIONAL DEPOSITORY AUTHORITY

Name: Dr D H Lewis

Address: ECACC
CAMR
Porton Down
Salisbury SP4 OJG

Signature(s) of person(s) having the power to represent the International Depository Authority or of authorized officials(s):

Date: 14/6/01

1 Where Rule 6.4(d) applies, such date is the date on which the status of international depositary authority was acquired

BUDAPEST TREATY ON THE INTERNATIONAL
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS
FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

TO
Dr N Osterrieder
Federal Research Centre
for Virus Diseases of Animals
Institue of Molecular Biology
Bodden Blick 5A
Insel Riens
D-17498
Germany

NAME AND ADDRESS OF THE PARTY TO WHOM THE VIABILITY OF STATEMENT IS ISSUED

VIABILITY STATEMENT
Issued pursant to Rule 10.2 by the
INTERNATIONAL DEPOSITARY AUTHORITY
identified on the following page

I. DEPOSITOR	II. IDENTIFICATION OF THE MICROORGANISM
me: Dr N Osterrieder Federal Research Centre for Virus Diseases of Animals Institue of Molecular Biology Address: Bodden Blick 5A Insel Riens D-17498 Germany	Accession number given by the INTERNATIONAL DEPOSITORY AUTHORITY: 01032704 Date of the deposit or of the transfer: 27 March 2001

II. VIABILITY STATEMENT

The viability of the microorganism identified under II above was tested on 27 March 2001 [2]. On that date, the said microorganism was

[X] [3] viable

[ ] [3] no longer viable

1 Indicate the date of the original deposit or, where a new deposit or a transfer has been made, the most relevant date (date of the new deposit or date of the transfer).

2 In the cases referred to in Rule 10.2 (a) (ii) and (iii), refer to the most recent viability test.

3 Mark with a cross the applicable box.

IV. CONDITIONS UNDER WHICH THE VIABILITY TEST HAS BEEN PERFORMED [4]	
Presence of DNA confirmed by Gel Electrophoresis using appropriate molecular weight markers, on a 1% Tris Borate EDTA Agarose Gel. Gel reference number 01/001 DNA Patent Book P158-159	
II. INTERNATIONAL DEPOSITARY AUTHORITY	
Name: Dr D H Lewis ECACC CAMR Address: Porton Down Salisbury Wiltshire SP4 0JG	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s): Date: 14/6/07.

4 Fill in if the information has been requested and if the results of the test were negative.

Form BP/9 (second and last page)

Bundesforschungsanstalt
für Viruskrankheiten der Tiere
Federal Research Centre
for Virus Diseases of Animals

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An:
Boehringer Ingelheim
Attn Dr. Thomas Klein
Vetmedica GmbH
Binger Str. 173
55126 Ingelheim

Tho whom it may concern

I, Dr. Osterrieder, the depositor of the biological material deposited at the ECACC with the accession number 01032704, authorise the applicant "Boehringer Ingelheim Vetmedica GmbH" to refer to the deposited biological material in the application and give my unreserved and irrevocable consent to the deposited material being made available to the public in accordance with the Budapest Treaty (28.04.1977) as well as with Rule 13bis PCT, Rule 28 EPC and in accordance with any other national patent law.

Insel Riems, 21-05-2002

Dr. Nikolaus Osterrieder